UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

KAREN SMART and STEVEN SMART, **Plaintiffs,** **v.** **BOSTON SCIENTIFIC CORPRORATOIN,** Serve: CSC-Lawyers Incorporating Service Company 221 Bolivar Street Jefferson City, MO 65101 **Defendant.**	**Case No.:**

COMPLAINT

Come Now, Plaintiffs Karen Smart and Steven Smart, and for their Complaint against Defendant Boston Scientific Corporation allege as follows:

THE PARTIES

1. Plaintiff Karen Smart is an adult individual, citizen, and resident of St. Louis County in the State of Missouri.

2. Plaintiff Steven Smart is an adult individual, citizen, and resident of St. Louis County in the State of Missouri.

3. Plaintiffs Benjamin Karen Smart and Steven Smart were married at all relevant times herein.

4. Defendant Boston Scientific is a Delaware corporation with its corporate headquarters in Massachusetts. Boston Scientific designed, manufactured, packaged, labeled,

marketed, sold and distributed the Advantage Transvaginal Mid-Urethral Sling System, including that which was implanted in the Plaintiff.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over this action pursuant to the diverse citizenship of the parties. 28 USCS § 1332(a)(2). Plaintiffs are citizens and residents of Missouri. Defendant Boston Scientific has a principal place of business in Massachusetts.

6. Personal jurisdiction exists over Defendant in the U.S. and in Missouri due to the general and specific contacts it maintains. Defendant maintains those contacts presently and did so at all times material to this action. Moreover, this Court has specific jurisdiction over this matter as Plaintiff was injured by Defendant's product in Missouri. Finally, the amount in controversy exceeds $75,000.

7. Venue is proper in the Eastern District of Missouri pursuant to 28 U.S.C. § 1391 as a substantial part of the events and/or omissions giving rise to the Plaintiff's claims emanated from activities within this jurisdiction and Defendant conducts substantial business within this jurisdiction.

FACTUAL ALLEGATIONS COMMON TO ALL COUNTS

8. Surgical mesh products have been used to repair abdominal hernias since the I950s. In the 1970s, gynecologists began using surgical mesh products designed for hernia repair for abdominal repair to surgically repair prolapsed organs. In the 1990s, gynecologists began using this surgical mesh for the surgical treatment of pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). Manufacturers, including Boston Scientific, began to modify the mesh used in hernia repair to be used as products specifically intended to correct POP and SUI.

9. Boston Scientific designs, manufactures, markets, packages, labels and sells

transvaginal mesh devices (hereinafter "Products"), which are comprised of implantable synthetic polypropylene surgical mesh sold for use in the female pelvic region to support and reinforce the body's pelvic organs and natural tissues for pelvic organ prolapse or stress urinary incontinence.

10. Transvaginal mesh devices, including those made by Boston Scientific that were implanted into Plaintiffs, have been linked by the FDA to complications that are unacceptably frequent and severe.

11. Boston Scientific's Products contain monofilament polypropylene mesh, and/or collagen. Despite claims that polypropylene is inert, the scientific evidence shows that this material as implanted in the relevant Plaintiff is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with Defendants' Pelvic Mesh Products. This negative response promotes inflammation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh. Furthermore, Defendants' collagen products cause hyper-inflammatory responses leading to problems including chronic pain and fibrotic reaction. Defendants' collagen products disintegrate after implantation in the female pelvis. The collagen products cause adverse tissue reactions, and are causally related to infection, as the collagen is a foreign organic material from animals. Cross linked collagen is harsh upon the female pelvic tissue. It hardens in the body. When mesh is inserted in the female body according to the manufacturers' instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

12. Defendants sought and obtained FDA clearance to market the Product under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is

required, and no formal review for safety or efficacy was ever conducted with regard to the Products.

13. On July 13, 2011, the FDA issued a Safety Communication with respect to similarly designed devices for pelvic organ prolapse ("POP") wherein the FDA stated that "serious complications associated with surgical mesh for transvaginal repair of the POP are *not rare*…" (emphasis in original). Pelvic Mesh for the treatment of SUI is similarly defective such that any statements made by the FDA with respect to POP devices should have placed Defendants on notice of the defects and hazards associated with their SUI products.

14. The FDA Safety Communication also stated, "*Mesh contraction* (shrinkage) is a *previously unidentified risk* of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA… Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain." (emphasis in original).

15. In a December 2011 Joint Committee Opinion, the American College of Obstetricians and Gynecologists ("ACOG") and the American Urogynecologic Society ("AUGS") also identified physical and mechanical changes to the mesh inside the body as a serious complication associated with vaginal mesh, stating:

> There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh… Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable.

16. The ACOG/AUGS Joint Committee Opinion also recommended, among other things, that "[p]elvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk."

17. The injuries of Plaintiffs are reported in the FDA Safety Communication and in the ACOG/AUGS Joint Committee Opinion.

18. The FDA Safety Communication further indicated that the benefits of using transvaginal mesh products instead of other feasible alternatives did not outweigh the associated risks.

19. Specifically, the FDA Safety Communication stated: "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk."

20. Contemporaneously with the Safety Communication, the FDA released a publication titled "Urogynecological Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse" (the "White Paper"). In the White Paper, the FDA noted that published, peer-reviewed literature demonstrates that "[p]atients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh."

21. The FDA summarized its findings from its review of the adverse event reports and applicable literature stating that it "has NOT seen conclusive evidence that using transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risk." (Emphasis in original).

22. The FDA White Paper further stated that "these products are associated with serious adverse events… Compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair."

23. In its White Paper, the FDA advises doctors to, *inter alia*, "[r]ecognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related

complications."

24. The FDA concludes its White Paper by stating that it "has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse."

25. Defendants knew or should have known about the Products' risks and complication identified in the FDA Safety Communication and the ACOG/AUGS Joint Committee Opinion.

26. Defendants knew or should have known that the Products unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks.

27. The scientific evidence shows that the material from which Boston Scientific's Products are made is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the Products, including the female Plaintiffs.

28. This negative response promotes inflammation of the pelvic tissue and contributes to the formation of severe adverse reactions to the mesh, such as those experienced by the female Plaintiffs.

29. The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problem code." "Material fragmentation" is defined as an "[i]ssue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction." The Products were unreasonably susceptible to degradation and fragmentation inside the body.

30. The Products were unreasonably susceptible to shrinkage and contraction inside the

body.

31. The Products were unreasonably susceptible to "creep" or the gradual elongation and deformation when subject to prolonged tension inside the body.

32. The Products have been and continue to be marketed to the medical community and to patients as safe, effective, reliable, medical devices, implanted by safe and effective, minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatments stress urinary incontinence and pelvic organ prolapse, and other competing products.

33. Boston Scientific omitted the risks, dangers, defects, and disadvantages of the Products, and advertised, promoted, marketed, sold and distributed the Products as a safe medical device when Boston Scientific knew or should have known that the Products were not safe for their intended purposes, and that the Products would cause, and did cause, serious medical problems, and in some patients, including Plaintiffs, catastrophic injuries.

34. Contrary to Boston Scientific's representations and marketing to the medical community and to the patients themselves, the Products have high rates of failure, injury, and complications, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiffs, making it defective under the law.

35. The specific nature of the Products' defects include, but is not limited to, the following:

(a) the use of polypropylene and collagen material in the Products and the immune reaction that results from such material, causing adverse reactions and injuries;

(b) the design of the Products to be inserted into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

(c) biomechanical issues with the design of the Products, including, but not limited to, the propensity of the Products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

(d) the use and design of arms and anchors in the Products, which, when placed in the women, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region;

(e) the propensity of the Products for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

(f) the inelasticity of the Products, causing them to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking); and

(g) the propensity of the Products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

(h) the hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

(i) the propensity of the collagen products to disintegrate after implantation in

the female pelvis, causing pain and other adverse reactions;

(j) the adverse tissue reactions caused by the collagen products, which are causally related to infection, as the collagen is a foreign organic material from animals;

(k) the harshness of cross linked collagen upon the female pelvic tissue, and the hardening of the products in the body;

(l) the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanted according to the manufacturers' instructions.

36. The Products are also defective due to Boston Scientific's failure to adequately warn or instruct Plaintiffs and/or her health care providers of subjects including, but not limited to, the following:

(a) the Products' propensity to contract, retract, and/or shrink inside the body;

(b) the Products' propensity for degradation, fragmentation and/or creep;

(c) the Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

(d) the rate and manner of mesh erosion or extrusion;

(e) The risk of chronic inflammation resulting from the Products;

(f) the risk of chronic infections resulting from the Products;

(g) the risk of permanent vaginal or pelvic scarring as a result of the Products;

(h) the risk of recurrent, intractable pelvic pain and other pain resulting from the Products;

(i) the need for corrective or revision surgery to adjust or remove the

Products;

(j) the severity of complications that could arise as a result of implantation of the Products;

(k) the hazards associated with the Products;

(l) the Products' defects described herein;

(m) treatment of stress urinary incontinence and pelvic organ prolapse with the Products is no more effective than feasible available alternatives;

(n) treatment of stress urinary incontinence and pelvic organ prolapse with the Products exposes patients to greater risk than feasible available alternatives;

(o) treatment of stress urinary incontinence and pelvic organ prolapse with the Products makes future surgical repair more difficult than feasible available alternatives;

(p) use of the Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

(q) removal of the Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

(r) complete removal of the Products may not be possible and may not result in complete resolution of the complications, including pain.

37. Boston Scientific has underreported information about the propensity of the Products to fail and cause injury and complications, and has made unfounded representations regarding the efficacy and safety of the Products through various means and media.

38. Boston Scientific failed to perform proper and adequate testing and research in

order to determine and evaluate the risks and benefits of the Products.

39. Boston Scientific failed to design and establish a safe, effective procedure for removal of the Products, or to determine if a safe, effective procedure for removal of the Products exists.

40. Feasible and suitable alternatives to the Products have existed at all times relevant that do not present the same frequency or severity of risks as do the Products.

41. The Products were at all times utilized and implanted in a manner foreseeable to Boston Scientific, as Boston Scientific generated the instructions for use, created the procedures for implanting the device, and trained the implanting physicians.

42. Boston Scientific provided incomplete and insufficient training and information to physicians regarding the use of the Products and the aftercare of patients implanted with the Products.

43. The Products implanted in the Plaintiffs were in the same or substantially similar condition as they were when they left Boston Scientific's possession, and in the condition directed by and expected by Boston Scientific.

44. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with the Products include, but are not limited to, erosion, contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, chronic pelvic pain.

45. In many cases, including the Plaintiffs', women have been forced to undergo extensive medical treatment, including, but not limited to, operations to locate and remove the Products, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain

control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

46. The medical and scientific literature studying the effects of Boston Scientific's transvaginal mesh products, like those products implanted in Plaintiffs, has examined each of these injuries, conditions, and complications, and has reported that they are causally related to the Products.

47. Removal of the contracted, eroded and/or infected mesh can require multiple surgical interventions for removal of mesh and results in scarring on fragile compromised pelvic tissue and muscles.

48. At all relevant times herein, Boston Scientific continued to promote the Products as safe and effective even when no clinical trials had been done supporting long- or short- term efficacy.

49. In doing so, Boston Scientific failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Products.

50. At all relevant times herein, Boston Scientific failed to provide sufficient warnings and instructions that would have put Plaintiffs and the general public on notice of the dangers and adverse effects caused by implantation of the Products.

51. The Products as designed, manufactured, distributed, sold and/or supplied by Boston Scientific were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Boston Scientific's knowledge of lack of safety.

52. As a direct and proximate result of the foregoing acts and omissions set forth in this Petition, Plaintiffs have:

(a) Suffered severe and permanent injuries which they will be forced to endure

for the remainder of their lives;

(b) Suffered physical impairment and disfigurement;

(c) Suffered physical pain and suffering;

(d) Suffered mental pain and suffering;

(e) Had their enjoyment of life severely impaired;

(f) Incurred and will continue to incur lost wages and loss of earning capacity;

(g) Incurred and will continue to incur various sums of money for past, present and future medical expenses associated with monitoring and treating their injuries, including but not limited to corrective surgery and hospitalization; and

(h) Incurred attorney's fees and expenses of litigation related to this action.

DISCOVERY RULE, TOLLING AND FRAUDULENT CONCEALMENT

53. Plaintiffs plead that the delayed discovery rule should be applied to toll the running of the statute of limitations until Plaintiffs knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that they had been injured, the cause of their injuries, and the tortious nature of the wrongdoing that caused their injuries.

54. Despite diligent investigation by Plaintiffs into the cause of their injuries, including consultations with Plaintiffs' medical providers, the nature of Plaintiffs' injuries and damages and their relationship to the Products and the Products' defects was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing each Plaintiffs' claims. Therefore, under appropriate application of the discovery rule, this suit was filed well within the applicable statutory limitations period.

55. The running of the statute of limitations in this cause is tolled due to equitable

tolling. Boston Scientific is estopped from asserting a statute of limitations defense clue to Boston Scientific's fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiffs and Plaintiffs' physicians of the true risks associated with Boston Scientific's transvaginal mesh devices. As a result of Boston Scientific's fraudulent concealment, Plaintiffs and Plaintiffs' prescribing physicians were unaware, and could not have known or have learned through reasonable diligence that Plaintiffs had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of Boston Scientific. Boston Scientific is estopped from asserting a statute of limitations defense because it fraudulently concealed from Plaintiffs the nature of Plaintiffs' injuries and the connection between the injuries and Boston Scientific's tortious conduct.

COUNT I

STRICT PRODUCT LIABILITY – DEFECTIVE DESIGN OR MANUFACTURE

56. Plaintiffs hereby incorporate by reference all above allegations as if fully set forth herein and further state as follows:

57. At all times material hereto, Boston Scientific engaged in the business of selling, distributing, supplying, manufacturing, marketing and promoting transvaginal mesh devices, which are defective and unreasonably dangerous to consumers, including Plaintiffs.

58. At all times material hereto, the transvaginal mesh devices manufactured by Boston Scientific were defective and unreasonably dangerous to Plaintiffs and other foreseeable users at the time they left the control of Boston Scientific.

59. At all times material hereto, the transvaginal mesh devices manufactured by Boston Scientific were expected to reach, and did reach, consumers, including Plaintiffs, without substantial change in the condition in which they were sold.

60. Plaintiffs were of the type of patients and consumers that Boston Scientific could reasonably expect would be prescribed and would use the transvaginal mesh devices manufactured by Boston Scientific.

61. The transvaginal mesh devices manufactured by Boston Scientific were defective and unreasonably dangerous when the products were initially patented, subsequently when they were promoted, when they were placed into the stream of commerce and when they were received by Plaintiffs in ways which include, but are not limited to, one or more of the following particulars:

(a) When placed in the stream of commerce, the transvaginal mesh devices contained unreasonably dangerous design defects and were not reasonably safe as intended to be used, subjecting Plaintiffs to risks which exceeded the benefits;

(b) When placed in the stream of commerce, the transvaginal mesh devices were defective in design and formulation, making use of them more dangerous than an ordinary physician or consumer would expect and more dangerous than other risks associated with the treatment of pelvic organ prolapse and stress urinary incontinence;

(c) The transvaginal mesh devices were insufficiently tested;

(d) The transvaginal mesh devices caused harmful side effects which outweigh any potential utility;

(e) The transvaginal mesh devices were not accompanied by adequate instructions and/or warnings to fully apprise consumers, including Plaintiffs, of the full nature and extent of the risks and side effects of the transvaginal mesh devices that were known or reasonably scientifically knowable at the

time the products left the possession of Boston Scientific;

(f) The warnings or instructions provided by Boston Scientific were not of a nature that a reasonably prudent medical device company in the same or similar circumstances would have provided with respect to the danger. There were no warnings or instructions that communicated sufficient information on the dangers of the transvaginal mesh devices and their defects, taking into account the characteristics of the products and the ordinary knowledge common to the physicians and the consumers, such as Plaintiffs, who purchase the product;

(g) The transvaginal mesh devices were further defective due to inadequate post-marketing warning or instruction because Boston Scientific knew of the risk of injury but failed to promptly investigate, respond to and warn about adverse effects revealed by post-marketing adverse event reports; and

(h) Boston Scientific knew, or in light of reasonably available scientific knowledge should have known about the danger that transvaginal mesh devices would cause the injuries for which Plaintiffs seek recovery. A reasonably competent physician using transvaginal mesh devices would not realize the dangerous condition of the transvaginal mesh devices.

62. As a direct and legal consequence of the defective condition of the transvaginal mesh devices, Plaintiffs have sustained serious and permanent injuries.

63. As a result of the injuries suffered due to the use of the transvaginal mesh devices, Plaintiffs have endured pain and suffering, disability or physical impairment, mental anguish, inconvenience, loss of capacity for the enjoyment of life experienced in the past or to be experienced

in the future, expense of hospitalization, medical and nursing care and treatment, loss of earnings and loss of the ability to earn money in the future. Plaintiffs' injuries and damages are permanent and will continue into the future.

WHEREFORE, Plaintiffs demand judgment in their favor and against Boston Scientific in a sum in excess of $75,000; for costs herein incurred; for attorney's fees; and for such other and further relief as this Court deems just and proper.

COUNT II

STRICT PRODUCT LIABILITY – FAILURE TO WARN

64. Plaintiffs hereby incorporate by reference all above allegations as if fully set forth herein.

65. Boston Scientific's transvaginal mesh devices were defective and unreasonably dangerous when they left the possession of Boston Scientific, in that they contained warnings insufficient to alert consumers, including Plaintiffs herein, to the dangerous risks and side effects associated with the devices.

66. Plaintiffs were implanted with transvaginal mesh devices for their intended purposes.

67. Plaintiffs could not have discovered the defects in the devices through the exercise of care.

68. Boston Scientific knew or should have known of the dangers associated with the devices and had a continuing duty to counsel and warn Plaintiffs of such dangers.

69. Boston Scientific failed to adequately warn consumers, including the Plaintiffs, of the dangers associated with transvaginal mesh devices. The warnings that were given by Boston Scientific were not accurate, adequate, complete or clear.

70. As a direct and legal consequence of the defective condition of the transvaginal

mesh devices, Plaintiffs have sustained serious and permanent injuries, have endured pain and suffering, disability or physical impairment, mental anguish, inconvenience, loss of capacity for the enjoyment of life experienced in the past or to be experienced in the future, expense of hospitalization, medical and nursing care and treatment, loss of earnings and loss of the ability to earn money in the future. Plaintiffs' injuries and damages are permanent and will continue into the future.

WHEREFORE, Plaintiffs demand judgment in their favor and against Boston Scientific in a sum in excess of $75,000; for costs herein incurred; for attorney's fees; and for such other and further relief as this Court deems just and proper.

COUNT III

NEGLIGENCE

71. Plaintiffs hereby incorporate by reference all above allegations as if fully set forth herein.

72. At all times relevant to this Complaint, Boston Scientific had a duty to properly manufacture, compound, test, inspect, package, label, distribute, market, examine, maintain, supply, and provide proper warnings for the transvaginal mesh devices.

73. Boston Scientific directly or indirectly, negligently and/or defectively, made, created, designed, developed, manufactured, assembled, tested, labeled, supplied, packaged, distributed, promoted, marketed, advertised, warned and/or sold in interstate commerce, and in the State of Missouri, transvaginal mesh devices.

74. Boston Scientific knew or should have known that the use of transvaginal mesh devices created an unreasonable risk of injury as a result of their design, testing, manufacturing, marketing and inadequate warnings.

75. Boston Scientific was negligent, and breached duties owed to Plaintiffs in the following regards:

(a) Despite knowledge of injurious side effects, failing to accompany the transvaginal mesh devices with adequate warnings and instructions regarding the adverse effects associated with the product's foreseeable use by Plaintiffs;

(b) Failing to adequately and properly test the transvaginal mesh devices before placing them on the market and after they were on the market. Specifically, Boston Scientific failed to conduct sufficient testing on the transvaginal mesh devices which, if properly performed would have shown that they had serious side effects;

(c) Failing to conduct adequate post-marketing surveillance and testing to determine the safety of the products. This is so even after numerous reports of adverse events were reported to Boston Scientific;

(d) Failing to provide adequate post-marketing warnings or instructions after Boston Scientific knew or should have known of the significant risks associated with the use of the devices;

(e) Despite knowledge of the danger, failing to adequately warn Plaintiffs and/or Plaintiffs' physicians that the use of the transvaginal mesh devices could result in injurious conditions;

(f) Despite the fact that they knew or should have known of the devices' dangers, Boston Scientific willfully and deliberately failed to adequately disclose the known or knowable risks associated with use in conscious

disregard of Plaintiffs' safety or welfare;

(g) Failing to adequately provide labeling to make known to the adverse effects of the transvaginal mesh devices;

(h) Failing to make a full disclosure of the adverse effects of transvaginal mesh devices;

(i) Continuing to manufacture, inadequately label and market for profit transvaginal mesh devices when the adverse health effects of the devices were known to create a substantial risk to the health of persons using them; and

(j) Failing to exercise the degree of care and caution that a reasonable, prudent manufacturer would exercise in the same or similar circumstances.

76. As a result of Boston Scientific's negligence and their willful and wanton misconduct, their transvaginal mesh devices were used by Plaintiffs thereby causing Plaintiffs to sustain reasonably foreseeable serious and permanent damages and injuries as alleged in this complaint. The negligence of Boston Scientific was a proximate cause of Plaintiffs' harm and injuries.

77. Boston Scientific's conduct fell below the required standard of care in that it failed to comply with the minimal standards of conduct adhered to by reasonably prudent manufacturers of medical devices, and the minimal standards of conduct adhered to by a reasonably prudent manufacturer when preparing consumer warnings and information in connection with medical devices.

78. The negligence described above directly and proximately caused Plaintiffs' injuries. Had Boston Scientific properly designed, adequately tested, properly responded to safety signals,

and provided full, complete, clear, truthful, and accurate warnings, Plaintiffs' physicians would not have used transvaginal mesh devices in Plaintiffs.

79. As a direct and legal consequence of Boston Scientific's negligence, Plaintiffs have sustained serious and permanent injuries and have endured pain and suffering, disability or physical impairment, mental anguish, inconvenience, loss of capacity for the enjoyment of life experienced in the past or to be experienced in the future, expense of hospitalization, medical and nursing care and treatment, loss of earnings and loss of the ability to earn money in the future. Plaintiffs' injuries and damages are permanent and will continue into the future.

WHEREFORE, Plaintiffs demand judgment in their favor and against Defendant Boston Scientific Corporation in a sum in excess of $75,000; for costs herein incurred; for attorney's fees; and for such other and further relief as this Court deems just and proper.

COUNT IV

NEGLIGENT DESIGN

80. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

81. Boston Scientific is liable to Plaintiffs under state common law and/or the applicable state Product Liability Acts for the negligent design of its transvaginal mesh devices.

82. At all times relevant to this lawsuit, Boston Scientific owed a duty to consumers, including Plaintiffs and their health care providers, to exercise reasonable care in the design of its transvaginal mesh devices.

83. Boston Scientific negligently and carelessly breached this duty of care to Plaintiffs because it designed its transvaginal mesh devices defectively. The defects include, but are not limited to:

(a) The material is not inert and therefore reacts to human tissues and/or other naturally occurring human bodily contents adversely affecting patient health;

(b) The mesh material harbors infections that adversely affect human tissues and patient health;

(c) The Products and the polypropylene material used to produce them migrate from the location of their implantation, adversely affecting tissues and patient health;

(d) The mesh material abrades tissues, adversely affecting patient health;

(e) The Products and the polypropylene material used to produce them regularly fail to perform the purpose of their implantation such that the patient requires removal of the device and repeated treatment and surgery;

(f) The Products and the polypropylene material used to produce them contracts, causes an acute inflammatory response, and becomes embedded in human tissue over time such that if' they need to be removed due to their various defects, the removal causes damage to organs and tissues, adversely affecting patient health; and

(g) The Products are defective in shape, composition, weight, physical, chemical and mechanical properties and are inappropriately engineered for use in the human body.

84. As a direct and legal consequence of Boston Scientific's negligent design of its transvaginal mesh devices, Plaintiffs have sustained serious and permanent injuries including but not limited to: pain and suffering, disability or physical impairment, mental anguish, inconvenience, loss of capacity for the enjoyment of life experienced in the past or to be experienced in the future,

expense of hospitalization, medical and nursing care and treatment, loss of earnings and loss of the ability to earn money in the future. Plaintiffs' injuries and damages are permanent and will continue into the future.

WHEREFORE, Plaintiffs demand judgment in their favor and against Defendant Boston Scientific Corporation in a sum in excess of $75,000; for costs herein incurred; for attorney's fees; and for such other and further relief as this Court deems just and proper.

COUNT V

FRAUD AND MISREPRESENTATION

85. Plaintiffs hereby incorporate by reference all above allegations as if fully set forth herein.

86. Boston Scientific fraudulently, intentionally and/or negligently misrepresented to the public and to Plaintiffs, both directly and by and tough Plaintiffs' physicians, the safety and effectiveness of the transvaginal mesh devices and/or fraudulently, intentionally, and or negligently concealed, suppressed or omitted material, adverse information regarding the safety and effectiveness of the transvaginal mesh devices.

87. Boston Scientific's intentional and/or negligent misrepresentations and omissions regarding the safety and efficacy of transvaginal mesh devices and their minimal side effects were communicated to Plaintiffs directly through promotional materials, advertising, and product inserts. The safety and efficacy of transvaginal mesh devices was also intentionally and/or negligently misrepresented to Plaintiffs' prescribing physicians with the intent that such misrepresentations would cause its transvaginal mesh devices to be used in Plaintiffs.

88. Boston Scientific knew or should have known that the representations they were making regarding the transvaginal mesh devices' safety, efficacy and minimal side effects were

false.

89. Boston Scientific made the misrepresentations and/or actively concealed, suppressed, or omitted this material information with the intention and specific desire that Plaintiffs, Plaintiffs' physicians, and the consuming public would rely on such misrepresentations in selecting its transvaginal mesh devices as the treatment for pelvic organ prolapse and stress urinary incontinence. Boston Scientific knew or should have known that Plaintiffs and Plaintiffs' physicians would rely upon their false representations.

90. Boston Scientific made these misrepresentations and actively concealed adverse information at a time when they, their agents and/or their employees knew, or should have known that the transvaginal mesh devices had defects, dangers, and characteristics that were other than what they had been represented to the medical community and the consuming public, including Plaintiffs herein. Specifically, Boston Scientific misrepresented, concealed, suppressed, or omitted that:

(a) There had been insufficient studies regarding the safety and efficacy of transvaginal mesh devices;

(b) Despite knowing that there had been insufficient or inadequate testing of the devices, they marketed, promoted, and/or sold the devices as if they had been fully and adequately tested;

(c) That Boston Scientific knew or should have known of reports of severe adverse reactions associated with use of the devices.

91. Adverse event information was strategically minimized, understated, or omitted in order to create the overall impression that the dangers were insignificant and infrequent.

92. The misrepresentations of and/or active concealment, suppression, and omissions by Boston Scientific were perpetuated directly and/or indirectly by Boston Scientific, their sales

representatives, employees, distributors, agents and/or detail persons.

93. The misrepresentations of and/or active concealment, suppression, and omissions by Boston Scientific constitute a continuing tort.

94. Through its product inserts, Boston Scientific continued to misrepresent the potential risks and complications associated with its transvaginal mesh devices.

95. Boston Scientific had a post-sale duty to warn physicians and Plaintiffs about the potential risks and complications associated with the devices it manufactured and sold in a timely manner.

96. If Plaintiffs and Plaintiffs' physicians had known the true facts concerning the risks of the use of transvaginal mesh devices, they would not have used the devices, and would have instead used one of the safer alternatives or no device at all.

97. The reliance of Plaintiffs and Plaintiffs' physicians upon the misrepresentations of Boston Scientific was justified, among other reasons, because said misrepresentations and omissions were made by individuals and entities who were in a position to know the true facts concerning transvaginal mesh devices while Plaintiffs and their physicians were not in a position to know the true facts, and because Boston Scientific overstated the benefits and safety of transvaginal mesh devices, and concomitantly downplayed the risks in their use, thereby inducing Plaintiffs' physicians to use transvaginal mesh devices, in lieu of other, safer alternatives.

98. As a direct and legal consequence of the acts and omissions set forth herein, Plaintiffs have sustained serious and permanent injuries including but not limited to: pain and suffering, disability or physical impairment, mental anguish, inconvenience, loss of capacity for the enjoyment of life experienced in the past or to be experienced in the future, expense of hospitalization, medical and nursing care and treatment, loss of earnings and loss of the ability to

earn money in the future. Plaintiffs' injuries and damages are permanent and will continue into the future.

WHEREFORE, Plaintiffs demand judgment in their favor and against Defendant Boston Scientific Corporation in a sum in excess of $75,000; for costs herein incurred; for attorney's fees; and for such other and further relief as this Court deems just and proper.

COUNT VI

BREACH OF EXPRESS AND IMPLIED WARRANTIES

99. Plaintiffs hereby incorporate by reference all above allegations as if fully set forth herein.

100. Boston Scientific, in the marketing, distribution and sale of transvaginal mesh devices for human use impliedly warranted that they were fit and safe as may be used by physicians.

101. Boston Scientific, in its product labeling, packaging, and promotional materials, expressly warranted to the medical community that transvaginal mesh devices were safe and fit for use in Plaintiffs and the general public for the treatment of pelvic organ prolapse and stress urinary incontinence. In actuality, transvaginal mesh devices were not fit, safe, effective or proper when used by physicians for recommended use.

102. Transvaginal mesh devices, in the composition and condition that they were marketed, distributed and sold to Plaintiffs were unsafe and unfit for use so as to be in breach of the express and implied warranties that they were fit for their intended purposes.

103. Plaintiffs and Plaintiffs' physicians relied upon the representations of Boston Scientific concerning the risks of the use of transvaginal mesh devices.

104. The reliance of Plaintiffs and Plaintiffs' physicians upon the misrepresentations of

Boston Scientific was justified, among other reasons, because said misrepresentations and omissions were made by individuals and entities that were in a position to know the true facts concerning transvaginal mesh devices while Plaintiffs and Plaintiffs' physicians were not in a position to know the true facts.

105. Plaintiffs and Plaintiffs' physicians would not have used transvaginal mesh devices, and would have used one of the safer alternatives, or no device at all, had adequate and accurate information regarding transvaginal mesh devices been provided to them.

106. As a direct and legal consequence of the acts and omissions set forth herein, Plaintiffs have sustained serious and permanent injuries including but not limited to: pain and suffering, disability or physical impairment, mental anguish, inconvenience, loss of capacity for the enjoyment of life experienced in the past or to be experienced in the future, expense of hospitalization, medical and nursing care and treatment, loss of earnings and loss of the ability to earn money in the future. Plaintiffs' injuries and damages are permanent and will continue into the future.

WHEREFORE, Plaintiffs demand judgment in their favor and against Defendant Boston Scientific Corporation in a sum in excess of $75,000; for costs herein incurred; for attorney's fees; and for such other and further relief as this Court deems just and proper.

COUNT VII

MISSOURI MERCHANDISING PRACTICES ACT

107. Plaintiffs reallege and incorporate herein by reference the foregoing allegations of this Petition as if fully set forth herein and further allege as follows:

108. Plaintiff brings this action as a consumer pursuant to R.S.Mo. §407.020 and 15 CSR60-8.020.

109. The Defendants were at all times relevant hereto lawfully doing business in the State of Missouri and this claim arose in St. Louis, State of Missouri.

110. At all times relevant, the Defendants sold and advertised for sale merchandise or services in trade or commerce, specifically their transvaginal mesh device.

111. During and before the time of the transaction referred to above, the Defendants engaged in unlawful practices as defined in R.S.Mo. §407.020 by misrepresenting the efficacy of their product to physicians and hospitals and by failing to warn of known defects in shape, composition, weight, physical, chemical and mechanical properties and are inappropriately engineered for use in the human body, which can cause debilitating injury and illness.

112. As a direct and proximate result of the aforementioned unfair practices and concealment, omission and suppression of material facts from Plaintiff's physicians and other health care providers, Plaintiff endured pain and suffering, disability or physical impairment, mental anguish, inconvenience, loss of capacity for the enjoyment of life experienced in the past or to be experienced in the future, expense of hospitalization, medical and nursing care and treatment, loss of earnings and loss of the ability to earn money in the future.

113. Plaintiff Karen Smart was directly and proximately harmed by the aforesaid violation of the Missouri Merchandising Practices Act by Defendants as described above, and she has suffered and will continue to suffer injuries, including but not limited to pain and suffering, disability or physical impairment, mental anguish, inconvenience, loss of capacity for the enjoyment of life experienced in the past or to be experienced in the future, expense of hospitalization, medical and nursing care and treatment, loss of earnings and loss of the ability to earn money in the future

114. Plaintiff has incurred and will incur attorney fees in prosecuting this action for which the Defendants are liable under R.S.Mo. §407.020.

115. The conduct of Defendants as described above demonstrated willful, wanton and malicious conduct, as well as a complete indifference to or conscious disregard for the safety of Plaintiff and others, thereby justifying an award of punitive damages in such sum which will serve to punish Defendants and to deter Defendants and others from like conduct in the future.

116. WHEREFORE, Plaintiffs demand judgment in their favor and against Defendant Boston Scientific Corporation in a sum in excess of $75,000; for costs herein incurred; for attorney's fees; and for such other and further relief as this Court deems just and proper.

COUNT VIII

LOSS OF CONSORTIUM

117. Plaintiffs hereby incorporate by reference all above allegations as if fully set forth herein.

118. At all times herein mentioned Plaintiffs and their aforementioned spouses were husband and wife.

119. As a direct result of Defendants' aforesaid conduct, Steven Smart has suffered a loss of consortium, services, society, companionship, love, affection, comfort, moral support and physical assistance in the operation and maintenance of the home, all to his general damage in an amount within the jurisdiction of this Court.

120. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe and debilitating injuries, pain and suffering, economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, and emotional distress.

WHEREFORE, Plaintiffs demand judgment in their favor and against Defendant Boston Scientific Corporation in a sum in excess of $75,000; for costs herein incurred; for attorney's fees;

and for such other and further relief as this Court deems just and proper.

COUNT IX

PUNITIVE DAMAGES

121. Plaintiffs hereby incorporate by reference all above allegations as if fully set forth herein.

122. While performing each of the acts and omissions previously set forth in this Petition, Boston Scientific actually knew of the defective nature of its products and the inadequacy of its warnings as set forth herein, yet Boston Scientific continued to design, manufacture, market, distribute, and sell their products in their defective condition so as to maximize sales and profits at the expense of Plaintiffs' health and the health of the consuming public.

123. The acts and omissions of Boston Scientific involved an extreme degree of risk, given the probability and magnitude of the potential harm, of causing harm to Plaintiffs and others.

124. Boston Scientific had actual; subjective awareness of the risk of injury posed by its transvaginal mesh devices to consumers such as Plaintiffs, A reasonable company in the position of Boston Scientific would have been aware of the risk of injury posed to consumers by the use of transvaginal mesh devices. Yet, Boston Scientific proceeded in conscious disregard to the rights, safety and welfare of Plaintiffs.

125. The acts and omissions of Boston Scientific demonstrate that they did not care about the peril in which they placed Plaintiffs, such that their conduct was grossly negligent and in conscious disregard of the safety of others, including Plaintiffs herein.

126. The conduct of Boston Scientific, as set forth above; was willful, wanton, reckless, grossly negligent, malicious, oppressive and evidencing such an entire want of care as to raise the presumption of a conscious disregard for the rights and safety of consumers, including Plaintiffs.

Boston Scientific acted only out of self-interest and personal gain. Such conduct evidences a specific intent to cause harm to Plaintiffs as provided under Missouri law.

127. Accordingly, punitive damages should be imposed against Boston Scientific pursuant to Missouri and other applicable laws to punish and deter Boston Scientific from repeating or continuing such unlawful conduct. Plaintiffs are entitled to recover punitive damages based upon the acts and omissions of Boston Scientifics as specifically pled herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendant Boston Scientific Corporation as follows:

1. For general damages in a sum exceeding this Court's jurisdictional minimum;
2. For reasonable medical expenses according to proof;
3. For all damages as allowed by law;
4. For prejudgment interest and post judgment interest as allowed by law;
5. For punitive and exemplary damages as allowed by law;
6. For the costs of suit herein incurred; and
7. For such other and further relief as this Court may deem just and proper.

JURY TRIAL DEMANDED

THE SIMON LAW FIRM, P. C.

By: /s/ Amy Collignon Gunn
Amy Collignon Gunn #45016
800 Market Street, Suite 1700
St. Louis, Missouri 63101
Phone: (314) 241-2929
Fax: (314) 241-2029
Email: agunn@simonlawpc.com
Attorneys for Plaintiffs